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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/800,448 | 03/05/2001 | Santu Bandyopadhyay | A34065 | 2808 |

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| EXAMINER | |
|---|---|
| EWOLDT, GERALD R | |
| **ART UNIT** | **PAPER NUMBER** |
| 1644 | |

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/800,448 | BANDYOPADHYAY ET AL. | |
| | Examiner | Art Unit | |
| | G. R. Ewoldt, Ph.D. | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 March 2004 and 21 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *14-34* is/are pending in the application.

4a) Of the above claim(s) *23-26,29-31 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,14-22,27,28 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

**DETAILED ACTION**

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendments and remarks filed 3/17/04 and 5/21/04 have been entered.

2. Claims 14-33, and newly added Claim 34, are pending.

3. Applicant has requested the rejoinder of Claims 31 and 32 indicating in the interview of 3/03/04 and the remarks of 3/17/03 that the invention of the instant claims is a method of producing mature dendritic Langerhans's cells. Accordingly, the invention under examination is a method of producing mature dendritic Langerhans's cells. It is clear, however, that a mature dendritic Langerhans's cell is distinct from a dendritic Langerhans's cell. See, for example, page 1 of the specification wherein it is disclosed that, " The best characterized immature DCs is [*sic*] the Langerhans cells (LC)". The specification also discloses that the cells produced by the method of Caux et al. (1992) are "dendritic Langerhans's cells". It is well-established that the cells of Caux et al. are immature and when removed from exogenous cytokines revert to an even more immature state. Because methods of producing "mature dendritic Langerhans's cells" are under examination, methods of producing immature "dendritic Langerhans's cells" have been withdrawn.

4. Claims 23-26, 29-31, and 34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 14-22, 27-28, and 32-33 are being acted upon.

5. In view of Applicant's amendments and remarks all previous rejections have been withdrawn.

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

A) the invention of Claim 14, a method comprising culture "at about 30°C to about 40°C",

B) the invention of Claim 15, comprising "the exogenous cytokine is granulocyte colony stimulating factor or interleukin-4",

C) the invention of Claim 17, a method comprising culture "for a period of about 2 to about 8 days",

D) the invention of Claim 19, a method "wherein the medium contains at least about 2% fetal calf serum",

E) the invention of Claim 20, a method "wherein the fetal calf serum is about 10%",

F) the invention of Claim 21, a method "wherein human platelets are added to the medium",

G) the invention of Claim 22, a method "wherein rat platelets are added to the medium containing mice blood cells",

7. The following are new grounds for rejection.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 14-22 and 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically, the claims are vague and indefinite in that the product of the claims, "mature dendritic Langerhans's cells", is not the intended product "dendritic Langerhans's cells", set forth in the preamble of independent Claims 14 and 28. Additional, references to the intended product in Claims 21, 22, and 27 also improperly recite "dendritic Langerhans's cells".

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 14-22, 27-28, and 32-33 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed

invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) a method comprising a medium containing mammalian platelets that results in mature Langerhans' cells,

B) the method of Claim 33 wherein more than about 50% of the mature dendritic cells have dendritic processes and display reactivity to anti-HLA-DR, anti-CD40, and anti-CD86 monoclonal antibodies and less than about 20% of the mature dendritic cells display reactivity to anti-CD1a, anti-CD80, and anti-CD83 monoclonal antibodies.

Upon careful review of the specification no support has been found for the broadening of the instant invention, i.e., A) the use of mammalian platelets to produce mature dendritic Langerhans' cells of any species or B) the use of specific results in generic claims.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 14-17, 21, 28 and 32-33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Semple et al. (1991).

Semple et al. teaches an in vitro method for producing mature dendritic Langerhans cells, comprising culturing cells selected from the group consisting of peripheral blood monocytes and bone marrow cells in a medium (RPMI-1640) containing mammalian (human) platelets; and incubating the culture at about 30°C to about 40°C for a period (about 2 to about 8 days) sufficient to enable formation of mature dendritic Langerhans cells, wherein the medium omits an exogenous cytokine including GM-CSF or IL-4 (see particularly page 2620, *PBMC/platelet APC cultures*). Note that the intention of the method as set forth in Claim 21 adds no patentable weight to the method. The method of the reference performs the same steps as the method of the instant claims and would, thus, comprise the same results.

Likewise, the results of Claim 32 would also be inherent to the method of the reference.

The reference clearly anticipates the claimed invention.

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Semple et al. (1991).

Semple et al. has been described above. The reference teaching differs from the claimed invention only in that it does not teach the use of fetal calf serum in the method. The method of the reference employs human AB serum; it is well known, however, that fetal calf serum is a much cheaper substitute for human serum in cell culture methods wherein human serum is not required (i.e., methods wherein the product is not intended for administration to humans, such as the claimed method). Regarding concentrations of serum used in culture, the choice of serum concentrations comprises only routine optimization of the claimed method, said routine optimization falling well within the purview of one of skill in the art at the time of the invention.

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

18. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR

or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Inquiries of a general nature may also be directed to the Technology Center 1600 Receptionist at (571) 272-1600.

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1/26/04
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